

(parasitic stages) (*Hypoderma bovis*, *H. lineatum*); lice (*Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*); mites (*Psoroptes ovis* (syn. *P. communis* var. *bovis*), *Sarcoptes scabiei* var. *bovis*); and for control of infections of *D. viviparus* and *O. radiatum* for 28 days after treatment; *O. ostertagi*, *T. axei*, and *C. punctata* for 21 days after treatment; and *H. placei* and *C. oncophora* for 14 days after treatment.

(3) *Limitations*. For subcutaneous use only. Not for intravenous or intramuscular use. Do not treat cattle within 49 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. Do not use in other animal species because severe adverse reactions, including fatalities in dogs, may result. A withdrawal period has not been established for this product in prurminating calves. Do not use in calves to be processed for veal.

[55 FR 38984, Sept. 24, 1990, as amended at 62 FR 14302, Mar. 26, 1997; 62 FR 63271, Nov. 28, 1997; 64 FR 26671, May 17, 1999; 69 FR 31735, June 7, 2004; 72 FR 27734, May 17, 2007; 77 FR 64717, Oct. 23, 2012]

§ 522.1204 Kanamycin.

(a) *Specifications*. Each milliliter of solution contains 50 or 200 milligrams (mg) of kanamycin as kanamycin sulfate.

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount*. Administer by subcutaneous or intramuscular injection 5 mg per pound of body weight per day in equally divided doses at 12-hour intervals.

(2) *Indications for use*. For the treatment of bacterial infections due to kanamycin sensitive organisms in dogs and cats.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16190, Mar. 25, 2014]

§ 522.1222 Ketamine.

(a) *Specifications*. Each milliliter contains ketamine hydrochloride equivalent to 100 milligrams (mg) ketamine base activity.

(b) *Sponsors*. See Nos. 000859, 026637, 054628, 054771, 061690, and 063286 in § 510.600(c) of this chapter.

(c) *Special considerations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Cats*—(i) *Amount*. 5 to 15 mg/pound body weight intramuscularly, depending on the effect desired.

(ii) *Indications for use*. For restraint or as the sole anesthetic agent in diagnostic or minor, brief surgical procedures that do not require skeletal muscle relaxation.

(2) *Subhuman primates*—(i) *Amount*. 3 to 15 mg/kilogram body weight intramuscularly, depending upon the species, general condition, and age of the subject.

(ii) *Indications for use*. For restraint.

[67 FR 17283, Apr. 10, 2002, as amended at 73 FR 8192, Feb. 13, 2008; 74 FR 36111, July 22, 2009; 74 FR 66573, Dec. 16, 2009; 75 FR 10167, Mar. 5, 2010; 78 FR 21060, Apr. 9, 2013. Redesignated and amended at 79 FR 16191]

§ 522.1223 Ketamine, promazine, and aminopentamide.

(a) *Specifications*. Each milliliter of solution contains ketamine hydrochloride equivalent to 100 milligrams (mg) ketamine base activity, 7.5 (mg) of promazine hydrochloride, and 0.0625 mg of aminopentamide hydrogen sulfate.

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in cats*—(1) *Amount*. Administer by intramuscular injection 15 to 20 mg ketamine base per pound of body weight, depending on the effect desired.

(2) *Indications for use*. It is used in cats as the sole anesthetic agent for ovariohysterectomy and general surgery.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16191, Mar. 25, 2014]

§ 522.1225 Ketoprofen.

(a) *Specifications*. Each milliliter of solution contains 100 milligrams (mg) of ketoprofen.

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

§ 522.1242

(c) *Conditions of use in horses*—(1) *Amount*. Administer by intravenous injection 1.0 mg per pound of body weight once daily for up to 5 days.

(2) *Indications for use*. For alleviation of inflammation and pain associated with musculoskeletal disorders in horses.

(3) *Limitations*. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16191, Mar. 25, 2014]

§ 522.1242 Levamisole.

(a) *Specifications*. Each milliliter of solution contains levamisole phosphate equivalent to 136.5 or 182 milligrams of levamisole hydrochloride (13.65 or 18.2 percent).

(b) *Sponsor*. See Nos. 000061 and 057561 in § 510.600 of this chapter for use of 13.65 percent injection, and see No. 054771 for use of 13.65 and 18.2 percent injection.

(c) *Conditions of use*—(1) *Amount*. 2 milliliters per 100 pounds of body weight, subcutaneously in the neck.

(2) *Indications for use*. (i) The 13.65 percent injection is used as an anthelmintic in cattle for treatment of the following parasites: stomach worms (*Haemonchus*, *Trichostrongylus*, *Ostertagia*), intestinal worms (*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*, *Chabertia*), and lungworms (*Dictyocaulus*).

(ii) The 18.2 percent injection is used as an anthelmintic in cattle for treatment of the following parasites: stomach worms (*Haemonchus*, *Trichostrongylus*, *Ostertagia*), intestinal worms (*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*) and lungworms (*Dictyocaulus*).

(3) *Limitations*. Do not administer more than 10 milliliters per site. Cattle that are severely parasitized or maintained under conditions of constant helminth exposure may require retreatment within 2 to 4 weeks after first treatment. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Consult your veterinarian before using in severely debilitated animals or animals under severe stress. Do not ad-

21 CFR Ch. I (4–1–14 Edition)

minister to cattle within 7 days of slaughter. Do not administer to dairy animals of breeding age.

[43 FR 20489, May 12, 1978, as amended at 43 FR 29289, July 7, 1978; 43 FR 60895, Dec. 29, 1978; 47 FR 10807, Mar. 12, 1982; 62 FR 61625, Nov. 19, 1997; 65 FR 61090, Oct. 16, 2000; 67 FR 63055, Oct. 10, 2002. Redesignated and amended at 79 FR 16191, Mar. 25, 2014]

§ 522.1260 Lincomycin.

(a) *Specifications*. Each milliliter of solution contains lincomycin hydrochloride monohydrate equivalent to:

(1) 25, 50, 100, or 300 milligrams (mg) lincomycin.

(2) 25, 100, or 300 mg lincomycin.

(3) 300 mg lincomycin.

(4) 100 or 300 mg lincomycin.

(b) *Sponsors*. See sponsors in § 510.600(c) of this chapter for uses as in paragraph (e) of this section.

(1) No. 054771 for use of concentrations in paragraph (a)(1) of this section as in paragraph (e) of this section.

(2) Nos. 000859 and 058005 for use of concentrations in paragraph (a)(2) of this section as in paragraph (e)(2) of this section.

(3) No. 054771 for use of concentration in paragraph (a)(3) of this section as in paragraph (e)(2) of this section.

(4) No. 061623 for use of concentrations in paragraph (a)(4) of this section as in paragraph (e)(2) of this section.

(c) *Special considerations*. When common labeling for use of the drug in dogs, cats, and swine is included with the drug, all such uses are subject to the labeling requirements of § 201.105 of this chapter.

(d) *Related tolerances*. See § 556.360 of this chapter.

(e) *Conditions of use*. It is used for animals as follows:

(1) *Dogs and cats*—(i) *Amount*. 5 mg per pound (lb) of body weight twice daily or 10 mg/lb body weight once daily by intramuscular injection; 5 to 10 mg/lb body weight one or two times daily by slow intravenous injection.

(ii) *Indications for use*. Infections caused by Gram-positive organisms, particularly streptococci and staphylococci.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.